Examiner contends Applicant elected claims 1, 3, 18 and 20 without traverse, however, Applicant traversed the restriction requirement. Specifically, Applicant requested reconsideration of the restriction requirement and stated that it was Applicant's belief that to fully protect the invention, each of the claims should remain in a single application. Applicant again requests that the restriction requirement be withdrawn.

Upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependant form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141.

The Examiner has cited 35 U.S.C. §101 and states that "use" claims are impermissible. No claims were rejected under 35 U.S.C. §101. Claims 9-20 have been written as "method" claims rather than "use" claims in view of 35 U.S.C. §101.

Claims 3, 18 and 20 have been rejected under 35 U.S.C. §112, second paragraph. To overcome the rejection of claim 3, claim 1 has been amended to provide an antecedent basis for the phrase "sclerosing substance" in claim 3. Claims 18 and 20, along with claims 9-17 and 19, have been amended to claim the present invention as a "method" rather than a "use" and to recite an active step (e.g., "injecting") in the claims as requested by the Examiner. Accordingly, Applicant respectfully requests that the rejection of claims 3, 18 and 20 under 35 U.S.C. §112, second paragraph be withdrawn.

Claims 1 and 3 have been rejected under 35 U.S.C. §103 as being unpatentable over Applicant's admission in view of Hilmann et al. The Examiner contends that Applicant admits that mixing sclerosing agents with air to form bubbles is known and that Hilmann discloses forming injectable microfoam. The Examiner concludes that it would

have been obvious to one of ordinary skill in the art to make an injectable microfoam of a sclerosing agent having a higher viscosity, extended useful lifetime and increased quantity based on the teachings of Hilmann and Applicant's admission.

The present invention is directed, *inter alia*, to injectable microfoams used for therapeutic uses which is prepared with a sclerosing substance such as sodium tetradecyl sulfate. Hilmann does not teach or suggest forming injectable microfoam for therapeutic uses.

Hilmann et al. describes a solution containing microbubbles used for ultrasonic diagnostics. (See for example col. 3, lines 8-10 "...this invention relates to a kit for preparing a liquid suspension of microbubbles..."; "...microbubbles are introduced into the selected liquid carrier..."; col. 7, lines 56-57 "...a suspension of microbubbles...".) Hilmann does not describe a microfoam but only a suspension of microbubbles in a liquid carrier.

The difference between a suspension of microbubbles and microfoam is illustrated in Exhibit 1 (attached). Figure A of Exhibit 1 shows schematically a suspension of microbubbles (mb) in a liquid carrier (lc). One way of describing a suspension of microbubbles is that the diameter of the gas bubbles is less than the distance between the bubbles. These types of systems are often referred to as "gas emulsions", "gas solutions", or "gas dispersions".

In contrast to microbubbles, microfoam (illustrated in Figure B of Exhibit 1) consists of an agglomerate of bubbles which are not independent from each other, but which are merely separated by a thin liquid film. The gas is not contained as a number of bubbles

suspended in a carrier liquid. The difference between foam and a suspension of bubbles is clearly understood in the art. References which generally describe the difference between a "suspension of bubbles" and "foam" are attached at Exhibit 2 for the Examiner's consideration. Even Hilmann distinguishes a suspension of microbubbles from foam. (See e.g., col. 7, lines 13-15 and lines 45-46).

In addition to being structurally different, microfoam of this invention is also functionally different from the suspension of microbubbles described by Hilmann. The present invention uses microfoam in a number of therapeutic applications that could not successfully employ using the suspension of microbubbles of Hilmann. For example, the present invention uses a block of microfoam to produce an intravascular "block" displacement of blood in the free space inside the vessel, thereby creating homogenous contact between the sclerosing substance and the inside walls of the vessel. The microbubbles of Hilmann would not be able to achieve an intravascular "block" displacement of blood. Moreover the concentration of the sclerosing substance inside the vessel and the time the sclerosing substance is in contact with the vessel can be easily controlled with the microfoam of the present invention while microbubbles do not permit the same degree of control.

Applicants submit that one skilled in the art attempting to produce the microfoam of the present invention for therapeutic applications would not look to the teachings of Hilmann, which teaches using microbubbles for ultrasonic diagnostics. The Federal Circuit in *In re Deminski*, 796 F.2d 436 (Fed. Cir. 1986) outlined a two-step test to determine whether a prior art reference is nonanalogous and thus not relevant in determining

obviousness. Specifically, an Examiner must determine (1) whether the reference is "within the field of the inventor's endeavor" and (2) if not, determine whether the reference is "reasonably pertinent to the particular problem with the inventor was involved." *Id.* at 442. Hilmann is non-analogous art and inapplicable to the present invention under *In re Deminski*. First, Hilmann is not directed to the therapeutic methods of this invention, it is it is directed to ultrasonic diagnostics. Second, Hilmann does not attempt to solve the problems of this invention, namely, using a sclerosing agent in a foam to displace the blood in the vein, thereby permitting contact between the sclerosis agent and the endothelium of the vein.

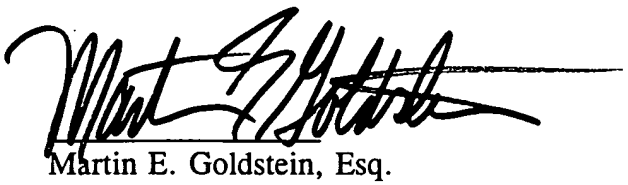
Moreover, the "advantages" the Examiner contends Hilmann identifies are advantages over traditional suspensions of microbubbles, not over foam. The fact that mixing sclerosing agents with air to form bubbles was known in the art (Orbach, 1946) does not cure the deficiencies of the teachings of Hilmann. There is nothing in the teachings of Hilmann that would induce a person skilled in the art to combine the teachings of Orbach in 1946 with the solution of microbubbles suggested by Hilmann to achieve the present invention.

Neither the teachings of Hilmann and Applicant's admissions, alone or in combination, teach the claimed invention. Accordingly, withdrawal of the rejection of claims 3, 18 and 20 under 35 U.S.C. §103 is requested.

In light of the above amendment and arguments, it is respectfully submitted that the present claims are in condition for allowance. A notice to this effect is earnestly solicited.

Reconsideration of the requirement for restriction and allowance of each of the presently pending claims are respectfully requested.

Respectfully submitted,



Martin E. Goldstein, Esq.
Reg. No. 20,869
Attorney for Applicant(s)

DARBY & DARBY, P.C.
805 Third Avenue
New York, New York 10022-7513
(212) 527-7700

M:\7723\0A975\MAP4765

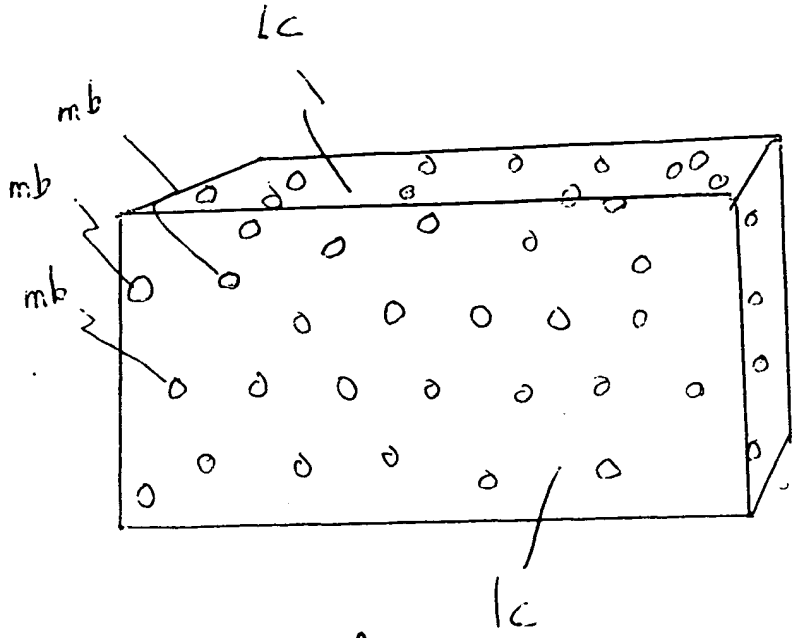


Fig A

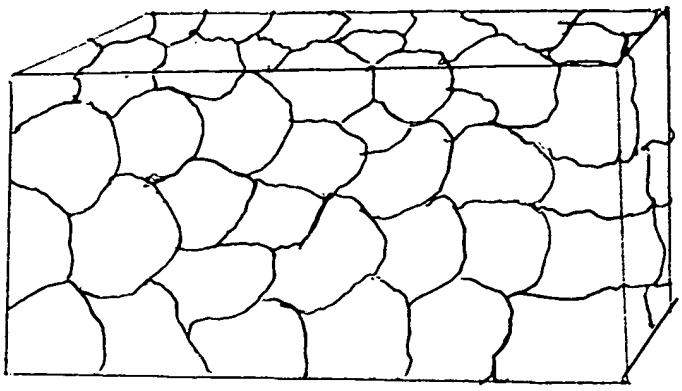


Fig B